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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,576	06/13/2001	Clifton A. Alferness	59013-331623	7153

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PATENT DOCKETING - INTELLECTUAL PROPERTY
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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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06/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/880,576	Applicant(s) ALFERNES ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,32-34,37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,32-34,37 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 and 27 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 27, 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 states the jacket is complaint *and elastic* (emphasis added). The Applicants, in previous responses argue US Pat No 5,702,343, incorporated by reference in its entirety in the current specification, discloses an elastic material. However, the Applicants have not specifically incorporated by reference the type of material for the heart jacket. The Applicants have only incorporated by reference the means of securing opposing edges

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on the jacket. Therefore, the current disclosure fails to support the use of an elastic material. See Zenon Environmental Inc. v. United States Filter Corp., 85 USPQ2d 1118 (Fed. Cir. 2007).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman et al (6,224,540 B1) in view of Jamshidi (5,593,428).

Lederman et al disclose a passive girdle for constraining heart expansion and further disclose accessing the heart (the heart has to be accessed in order to place jacket 30 on the heart); placing a jacket (30) on the heart, the jacket (30) comprising compliant and elastic (as explained in the Applicant's remarks filed on June 9, 2008, regarding the term "elastic"), open cell biocompatible material (33) around the ventricles of the heart to passively constrain circumferential expansion of the heart (See Column 5, lines 35-36); securing the jacket (30) on the heart (See Column 5, lines 52-55); the jacket (30) is secured to the heart using sutures (See Column 5, lines 52-55, attaching the device at 4-6 points along the A-V groove suggests the use of sutures because an adhesive would be incompatible on a beating heart); adjusting the jacket (30) to snugly conform to the external geometry of the heart (See Column 5, lines 55-57); and the

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jacket (30) is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume (See Column 5, lines 26-31, see explanation above).

Lederman et al however fail to disclose causing an electrical element to extend to the heart, to operatively engage the accessed heart to couple electrical therapy to the heart; the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy.

Jamshidi disclose a pacing and defibrillation means for providing therapy to a heart and further disclose causing an electrical element to extend to the heart, to operatively engage the accessed heart to couple electrical therapy to the heart (see Figure 4); the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy. See also Column 1, lines 66-67; Column 2, lines 1 and 43-53.

To provide the means of Lederman et al with an electrotherapy means would have been obvious to one of ordinary skill in the art, in view of the teachings of Jamshidi, since all of the claimed elements were known in the prior art and one skill in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e. one skilled in the art would have recognized that the electric therapy as taught by Jamshidi would provide the heart jacket of Lederman et al with an additional means of therapy to a heart already weakened by cardiomyopathy.

Response to Arguments

6. Applicant's arguments filed March 27, 2009 have been fully considered but they are not persuasive.

In the Advisory Action mailed on December 31, 2008, the Examiner had withdrawn the previous 112 rejection, with regards to the subject matter the Applicants argued was incorporated by reference. The Examiner with this Office Action has reinstated the 112 rejection, in light of *In re Zenon Environmental Inc.* In the court decision, the US Court of Appeals determined a limitation that is incorporated by reference must be specifically incorporated by reference, and not be incorporated by a broad incorporation of an entire patent. For instance, in the current application, in order to incorporate the type of material in US Pat No 5,702,343, the specification must specifically state "types of material and their properties as disclosed in US Pat No 5,702,343, which is incorporated herein by reference". However, the current specification only states: "Systems for securing the opposing edges are disclosed in, for example, U.S. Pat. No. 5,702,343, the entire disclosure of which is incorporated herein by reference." The current specification fails to disclose the incorporation by reference the type of material and the properties of said material. Therefore, the current specification fails to disclose the claimed limitation of an elastic material.

The Applicants argue Lederman et al fail to disclose an "elastic" material. Even though the current specification fails to support the "elastic" limitation, as discussed above, the Examiner would like to discuss the reference of Lederman et al with respect

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to the “elastic” limitation. The Examiner erroneously argued in the Advisory Action mailed on December 31, 2008 a different embodiment of Lederman et al. However, Lederman et al disclose in Figures 4 and 5, a heart jacket that is comprised of a plurality of plastic loops intertwined with one another to form the jacket. Column 5, lines 21-24, state: “The girdle 30 of Fig. 4 is an adjustable girdle made from a synthetic material that can limit tension, but is otherwise deformable to conform to the anatomical geometry of the heart.” Merriam-Webster’s Online Dictionary defines “elastic” as: “capable of being easily stretched or expanded and resuming former shape: flexible”. A material that can limit tension and be deformable to conform to a heart implies the material is elastic (flexible) to some extent; otherwise the jacket would not be able to conform to the beating heart. The jacket would be deformed once placed on the heart, but once removed from the heart, the material would return to the original configuration. In this instance, the elastic component is the entire jacket, not the individual rings that comprise the jacket.

The Applicants also argue the combination of Lederman et al and Jamshidi. The Applicants argue there is no teaching or suggestion in Lederman et al to utilize electrical therapy as disclosed in Jamshidi. As seen above, the prior art rejection of Lederman et al and Jamshidi is a rejection using KSR v. Teleflex. The current claims are nothing more than the combination of two very well known heart treatments: a heart jacket and electrical therapy. Furthermore, the combination of the Lederman et al and Jamshidi would not in any way change the function of either the jacket or the application of electrical therapy. The heart jacket of Lederman et al clearly disclose the use of an open

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cell jacket, which would clearly allow for the access to the heart tissue for the application of electrical therapy. Therefore, the prior art rejection is being maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmál/
Examiner, Art Unit 3736